Docket: 2780 (203-3093 PCT US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Bruce K. Jankowski	EXAMINER:	Victoria W. Chen
SERIAL NO.:	10/510,942	ART UNIT:	3739
FILED:	October 8, 2004	DATED:	May 14, 2010
TITLE:	**INSTRUMENT INTRODUCER**		

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P.O. Box 1450
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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action mailed on November 17, 2009 and an Advisory Action mailed on January 25, 2010 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20(b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: May 14, 2010

Julie Yanopulos

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and/or the assignee of Appellant's interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The status of the claims of this application is as follows:

Claims 1-23 are pending, stand finally rejected, and are being appealed.

An accurate copy of claims 1-23 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed January 25, 2010 indicates that the response to the Final Office Action of November 17, 2009, filed on January 13, 2010 (referred to in the Advisory Action under "Request for Reconsideration/Other") has been considered but that it allegedly failed to place the application in condition for allowance. The Advisory Action also indicates that proposed amendments (referred to in the Advisory Action under "Amendments") will not be entered for the purposes of appeal, however, no amendments to the claims were submitted with the response to the Final Office Action filed on January 13, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body opening of a patient. (*See, e.g.,* Specification page 2, lines 20-21). The assembly includes a surgical instrument "S" or "L" for performing a surgical procedure and an instrument introducer assembly 10 having a tubular body portion 12 defining a lumen 18 therethrough and having a proximal end and a distal end, and a distal end portion 14 secured to the distal end 12a of the tubular body portion 12. (*See, e.g.,* Specification page 6, lines 25-29 and page 7, lines 3-5 and 10-12). The distal end portion 14 defines a pocket 30 having an annular wall 22 with an axial length such that the annular wall 22 of the pocket 30 is substantially in contact with an outer surface of the surgical instrument "S" along substantially the length of the pocket 30 and includes a substantially planar distal end wall 20 configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument "S" to facilitate passage of the surgical instrument "S" in a sealing relation to the surgical instrument "S". (*See, e.g.,* Specification page 9, line 32 to page 10, line 21, and FIGS. 3 and 3A). The surgical instrument "S" stretches the distal end portion 14 of the instrument introducer 10 as it is advanced therethrough. (*See, e.g.,* Specification page 10, lines 13-21).

Independent claim 15 is directed to a surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body of a patient. (*See, e.g.,* Specification page 2, lines 20-21). The assembly includes a surgical instrument "S" for performing a surgical procedure and an instrument introducer assembly 10 having a hollow elongate cylindrical body 12 and an elastomeric cap 14 secured to the distal end

portion of the cylindrical body 12. (*See, e.g.,* Specification page 6, lines 25-29, page 7, lines 3-5 and 23-25, and page 7, line 32 to page 8, line 1). The hollow elongate cylindrical body 12 includes a distal end portion terminating in a distal edge 12a and a proximal end portion, and defines a central longitudinal axis "A". (*See, e.g.,* Specification page 7, lines 3-5 and 10-11). The cap 14 defines a pocket 30 having an annular wall 22 with an axial length such that the annular wall 22 of the pocket 30 is substantially in contact with an outer surface of the surgical instrument "S" along substantially the length of the pocket 30 and includes a substantially planar distal end wall 20 having an outer terminal edge and an annular side wall depending from the outer terminal edge thereof. (*See, e.g.,* Specification page 7, lines 23-25, page 9, line 32 to page 10, line 21, and FIGS 3 and 3A). The distal end wall 20 including an aperture 26 formed in the pocket 30 configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument "S" to facilitate passage of the surgical instrument "S" therethrough in a sealing relation to the surgical instrument "S", wherein a center of the aperture 26 is coaxially aligned with the central longitudinal axis "A". (*See, e.g.,* Specification page 7, lines 25-31 and page 10, lines 8-12). The surgical instrument "S" stretches the aperture 26 of the distal end wall 20 of the instrument introducer 10 as it is advanced therethrough. (*See, e.g.,* Specification page 10, lines 13-21).

Independent claim 21 is directed to a method of introducing a surgical instrument into a cavity or a body opening of a patient. (*See, e.g.,* Specification page 3, lines 32-33). The method includes providing a surgical instrument "S" or "L" for performing a surgical procedure and providing an instrument introducer assembly 10, wherein the instrument introducer 10 includes a hollow tubular body 12 having a distal end portion and a proximal end portion defining a lumen

18 therebetween, and a resilient cap 14 secured to the distal end of the tubular body 12, the cap 14 defining a pocket 30 having an annular wall 22 with an axial length such that the annular wall 22 of the pocket 30 is substantially in contact with an outer surface of the surgical instrument "S" along substantially the length of the pocket 30 and including a substantially planar distal end wall 20 having an aperture 26 formed therein. (*See, e.g.,* Specification page 6, lines 25-29, page 7, lines 3-12 and 23-25, page 9, line 32 to page 10, line 21, and FIGS. 3 and 3A). The method further includes inserting the distal end of the instrument introducer 10 into the cavity or body opening of the patient, inserting the surgical instrument "S" into the lumen 18 of the tubular body 12 of the instrument introducer 10 through a proximal end of the tubular body 12, and advancing the surgical instrument "S" through the lumen 18 of the tubular body 12 of the instrument introducer 10 thereby stretching the instrument introducer 10 such that the aperture 26 of the distal end wall 20 stretches and conforms to a shape of the outer surface of the surgical instrument "S" until a distal end of the surgical instrument projects out through the aperture 26 of the cap 14, wherein the cap 14 creates a seal around the perimeter of the surgical instrument "S" extending therefrom. (*See, e.g.,* Specification page 11, line 24 to page 12, line 2).

Independent claim 22 is directed to a method of introducing a surgical instrument into a cavity or a body opening of a patient. (*See, e.g.,* Specification page 3, lines 32-33). The method includes providing a surgical instrument "S" or "L" for performing a surgical procedure and providing an instrument introducer assembly 10, wherein the instrument introducer 10 includes a hollow tubular body 12 having a distal end portion and a proximal end portion defining a lumen 18 therebetween, and a resilient cap 14 secured to the distal end of the tubular body 12, the cap 14 defining a pocket 30 having an annular wall 22 with an axial length such that the annular wall

22 of the pocket 30 is substantially in contact with an outer surface of the surgical instrument "S" along substantially the length of the pocket 30 and including a substantially planar distal end wall 20 having an aperture 26 formed therein. (*See, e.g.,* Specification page 6, lines 25-29, page 7, lines 3-12 and 23-25, page 9, line 32 to page 10, line 21, and FIGS. 3 and 3A). The method further includes inserting a distal end of the surgical instrument "S" into a proximal end of the tubular body 12 of the instrument introducer 10, inserting the distal end of the surgical instrument "S", having the instrument introducer 10 placed thereon, into the cavity or body opening of the patient, and advancing the surgical instrument "S" through the instrument introducer 10 thereby stretching the instrument introducer 10 such that the aperture 26 of the distal end wall 20 stretches and conforms to a shape of the outer surface of the surgical instrument "S" until the distal end of the surgical instrument "S" projects out through the aperture 26 of the cap 14, wherein the cap 14 creates a seal around the perimeter of the surgical instrument "S" extending therefrom. (*See, e.g.,* Specification page 11, lines 9-23).

Independent claim 23 is directed to a surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body opening of a patient. (*See, e.g.,* Specification page 2, lines 20-21). The assembly includes a surgical instrument "S" or "L" for performing a surgical procedure and an instrument introducer assembly 10 including a tubular body portion 12 defining a lumen 18 therethrough and having a proximal end and a distal end, and a distal end portion 14 secured to the distal end of the tubular body portion 12. (*See, e.g.,* Specification page 6, lines 25-29 and page 7, lines 3-5 and 10-12). The distal end portion 14 defines a pocket 30 having a substantially circular distal end wall 20 having a diameter smaller than a diameter of the tubular body portion 12 and an annular wall 22

depending from the circular distal end wall 20 to the tubular body portion 12, wherein the annular wall 22 is configured and adapted to contact an outer surface of the surgical instrument "S" and facilitate passage of the surgical instrument "S" therethrough. (*See, e.g.,* Specification page 7, lines 23-25 and page 10, lines 1-21). The distal end wall 20 of the distal end portion 14 includes an aperture 26 formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument "S" in a sealing relation to the surgical instrument "S", wherein the surgical instrument "S" stretches the aperture 26 of the distal end wall 20 of the instrument introducer 10 as it is advanced therethrough, and further wherein the aperture 26 has a smaller diameter than a diameter of the circular distal end wall 20, and wherein the aperture 26 is provided with a region of weakened strength 26a. (*See, e.g.,* Specification page 10, lines 1-21 and page 8, lines 7-10).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant requests review of the following outstanding grounds of rejection:

A) The rejection of claims 1-13, 15-19, and 23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,074 to Turkel et al. (hereinafter, Turkel);

B) The rejection of claims 1-9, 11, 12, 15-19, and 21-23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,752,970 to Yoon (hereinafter, Yoon);

C) The rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No. 5,634,937 to Mollenauer et al. (hereinafter, Mollenauer); and

D) The rejection of claims 14 and 20 under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al. (hereinafter, Staskin).

VII. ARGUMENTS

A) Claims 1-13, 15-19, and 23 are patentable under 35 U.S.C, §102(b) over U.S. Patent No. 5,792,074 to Turkel et al.

Claims 1-13, 15-19, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,074 to Turkel et al. (hereinafter, Turkel).

Under 35 U.S.C. § 102(b), "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131.

Appellant respectfully submits that Turkel fails to disclose each and every element recited in independent claims 1, 15, and 23, either expressly or inherently, and the Examiner has failed to make a *prima facie* showing of anticipation.

1) Independent claim 1

Independent claim 1 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument,

wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough.

An exemplary illustration of an embodiment of the present application is shown in Figures 3 and 3A (reproduced below). The distal end portion defines a pocket 30 having an annular wall with an axial length and includes a substantially planar distal end wall configured and adapted to stretch and conform to the shape of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument. As illustrated and described in the specification, the annular wall is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and the distal end wall remains in contact with an outer surface of the surgical instrument "S" as the surgical instrument is advanced therethrough and stretches the instrument introducer.

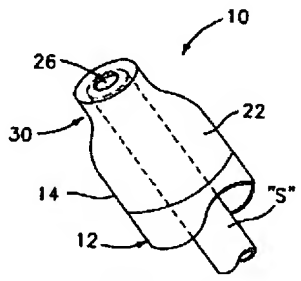

FIG. 3

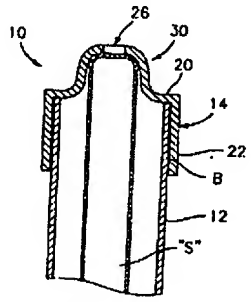

FIG. 3A

Turkel discloses, and illustrates in Figures 2a and 4 (reproduced below), a protected microbiological sampling brush assembly 10 including a sampling brush 12, an inner catheter 18 which houses the brush 12, an outer catheter 22 which houses the inner catheter 18, and an elastomeric tip 24 which is rigidly attached to the distal end 22a of the outer catheter 22. The elastomeric tip 24 is "substantially hemispherical" (see, claim 1) and has a weakened end in the

form of a distal slit 26. The distal slit 26 defines lips 26a and 26b which are parted by contact with distal end 18a of catheter 18 and thus, only the edge of lips 26a and 26b of tip 24 are in contact with the outer surface of catheter 18 as illustrated in FIG. 4.

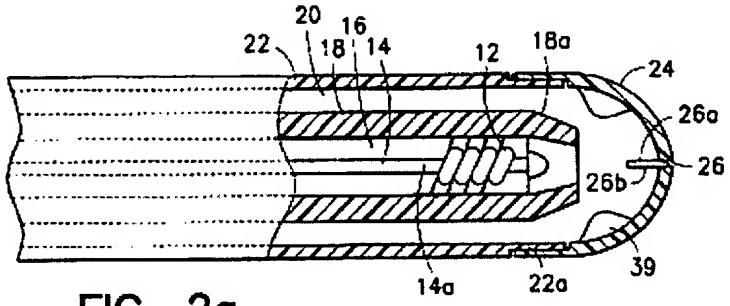

FIG. 2a

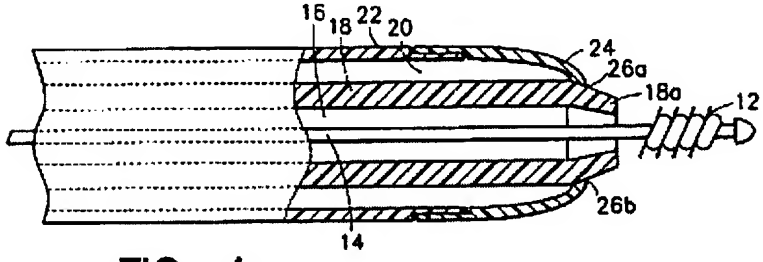

FIG. 4

Turkel fails to anticipate each and every element of claim 1, in that Turkel fails to disclose a pocket having an annular wall with an axial length such that the annular wall is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket. In contrast, Turkel only discloses the distal end 18a of catheter 18 contacting lips 26a and 26b of distal end 26 of outer catheter 22, and fails to disclose or illustrate the annular wall being in any contact with the surgical instrument along any portion of the length thereof.

As best seen in FIG. 4 of Turkel, since an open space or channel exists between distal end 18a of catheter 18 and control wire 14 of brush 12 (i.e., the surgical instrument), gases and/or fluid will readily enter into lumen 16 of catheter 18.

Moreover, Turkel also fails to disclose the pocket including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation to the surgical instrument. As discussed above, the distal end of Turkel is substantially hemispherical and Turkel only discloses parting of the lips upon movement of the inner catheter therethrough and sealing after withdrawal of the catheter from the elastomeric tip, not a pocket having an annular wall with an axial length that contacts the instrument and stretching of the distal end wall to conform to the shape of the inner catheter to facilitate passage in a sealing relation.

On page 2, paragraph 1 of the Advisory Action the Examiner states that:

> Applicant argues that Turkel fails to disclose a pocket with an annular wall with an axial length such that the annular wall is substantially in contact with an outer surface of the surgical instrument along the *[sic]* substantially the length of the pocket. As seen in the Final Rejection dated 11/17/09, the examiner included element 18, and thus 18a of Turkel as being part of the surgical instrument, and defined the annular wall of the pocket as being the portion of the wall of 24, labeled as 26a in Fig. 3 which is seen being in contact with the outer surface of 18. Applicant further argues that Turkel fails to teach a substantially planar distal end wall, because the shape of the end wall [24] as shown by Turkel in Figs. 2-4 is somewhat hemispherical. However, the examiner interprets the distal end wall disclosed by Turkel being substantially planar since planar is defined as "of, relating to, or lying in a plane" ["planar." Merriam-Webster Online Dictionary. 2010. Merriam-Webster Online. 18 January 2010, <http://www.merriam-webster.com/dictionary/planar>], and any surface if *[sic]* a three dimensional object is lying in a plane. The examiner further notes that there is no explanation or description of

> the distal end wall being substantially planar in applicant's specification.

Appellant submits that the Examiner's interpretation and application of Turkel is incorrect and clearly unreasonable. Pursuant to MPEP §2111, the Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Lip 26a of Turkel is not an annular wall of the pocket as suggested by the Examiner. As described in the disclosure of Turkel and shown in FIGS. 3 and 3A (reproduced above), lips 26a and 26b are a portion of distal slit 26 through which distal end 18a of inner catheter 18 can be moved. Nowhere does Turkel disclose that the lip is an annular wall of the pocket that is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket. Furthermore, the Examiner's interpretation of "planar" includes any three-dimensional shape.

Moreover, the Examiner's interpretation of the distal end wall of Turkel being substantially planar is a direct contradiction to the disclosure of Turkel which provides that the protected microbiological sampling brush assembly includes "e) automatic sealing means... comprising a substantially hemispherical elastomeric member" as recited in claims 1 and 4 of Turkel and also illustrated throughout the figures of Turkel. Thus, there is no teaching of a substantially planar distal end wall configured and adapted to stretch and conform to a shape of

the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation to the surgical instrument.

Accordingly, since Turkel does not disclose or suggest each and every element of claim 1, Appellant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Turkel should be reversed. Since claims 2-13 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Appellant respectfully submits that claims 2-13 are also not anticipated under 35 U.S.C. §102(b) over Turkel and the rejection of claims 2-13 should also be reversed.

2) Independent claim 15

The arguments presented above with respect to claim 1 apply with equal force to claim 15. In summary, it is the Appellant's position that the Examiner has failed to show how the prior art teaches each and every limitation of the claims and has incorrectly and unreasonably interpreted the Turkel reference to form the present rejection.

Independent claim 15 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a hollow elongate cylindrical body and an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining a pocket having a annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge thereof, the distal end wall

including an aperture formed in the pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

Since claim 15 requires that the surgical instrument contacts the annular wall of the pocket and stretches the aperture and/or distal end wall of the pocket, similar to claim 1, for at least the reasons that claim 1 is allowable over Turkel, Appellant submits that claim 15 is also allowable over Turkel.

Moreover, claim 15 also recites "the substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge." Turkel is devoid of this feature as the distal end of the outer catheter of Turkel is described and shown as being substantially hemispherical, thereby lacking a substantially planar distal end wall, as recited in claim 15.

Therefore, Appellant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Turkel should be reversed. Since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 1, Appellant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Turkel and the rejection of claims 16-19 should also be reversed.

3) **Independent claim 23**

Independent claim 23 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion defining a lumen therethrough and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of the surgical instrument and facilitate passage of the surgical instrument therethrough, wherein the distal end wall of the distal end portion includes an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough, and further wherein the aperture has a smaller diameter than a diameter of the circular distal end wall, and wherein the aperture is provided with a region of weakened strength.

Since claim 23 requires that the surgical instrument contact the annular wall of the pocket and stretch the aperture and/or distal end wall of the pocket, similar to claim 1, and since Turkel fails to disclose the annular wall being substantially in contact with an outer surface of the surgical instrument, it remains Appellant's position, for at least the reasons that claim 1 is allowable over Turkel, that claim 23 is also allowable over Turkel. Therefore, Appellant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Turkel should be reversed.

B) Claims 1-9, 11, 12, 15-19, and 21-23 are patentable under 35 U.S.C. §102(b) over U.S. Patent No. 5,752,970 to Yoon et al.

Claims 1-9, 11, 12, 15-19, and 21-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,752,970 to Yoon et al. (hereinafter, Yoon).

Appellant respectfully submits that the Examiner has failed to show how the prior art, namely Yoon, teaches all of the features of independent claims 1, 15, 21, 22, and 23. Accordingly, Appellant submits that the rejection of independent claims 1, 15, 21, 22, and 23, as well as claims 2-9, 11, and 12 which depend from claim 1 and claims 16-19 which depend from claim 15, should be reversed.

1) Independent claim 1

As stated above, independent claim 1 recites the distal end portion of the instrument introducer defining a pocket having an annular wall and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument.

Yoon discloses a cannula for introducing medical instruments into an anatomical cavity. The cannula includes an elongate tubular body defining a lumen and a valve protruding distally from the tubular body for preventing fluid flow through the lumen when medical instruments are withdrawn from the anatomical cavity into the tubular body. In embodiments, as illustrated in FIGS. 1 and 3 (reproduced below), the valve includes four valve members or flaps, each having "a generally spherical triangular shape to sealingly mate with one another when closed and to

form a hemispherical or rounded wall closing the distal end of the tubular body." (Yoon at column 4, lines 3-6).

In the Final Office Action, the Examiner asserts that FIG. 3 of Yoon illustrates the annular wall of the pocket being substantially in contact with an outer surface of a surgical instrument. Contrary to the Examiner's assertion, FIG. 3 of Yoon fails to illustrate the annular wall of a pocket being in contact with an outer surface of the surgical instrument along substantially the length of the pocket as FIG. 3 of Yoon merely illustrates a side view of the device. As stated above, the flaps are described as having "a generally spherical triangular shape." In view thereof, Appellants submit that Yoon fails to illustrate or disclose an annular wall that contacts the trocar and stretches it.

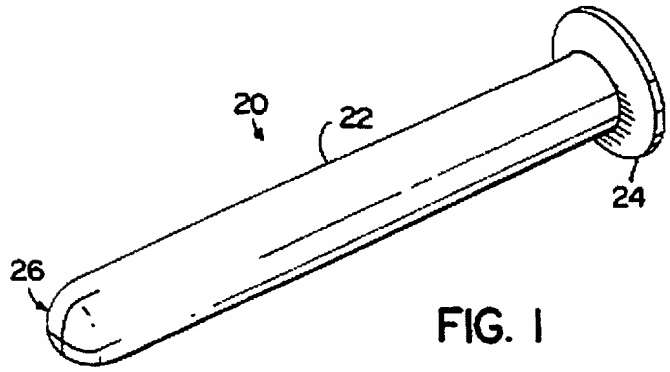

FIG. 1

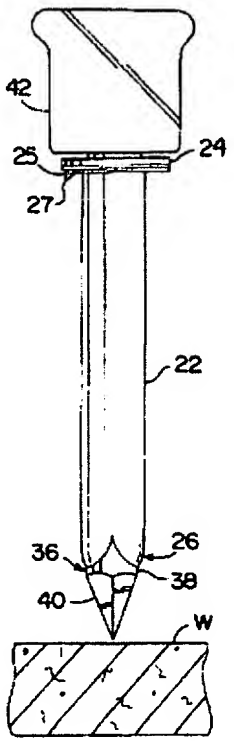

FIG. 3

In the Final Office Action, the Examiner pointed to the valve of FIG. 15 as disclosing a substantially planar distal end wall. However, this valve is described at column 7, lines 37-40 as being similar to the valve described above (i.e., having a hemispherical or rounded wall closing the distal end, as shown in FIG. 1), but also having the additional feature of being detachable. Thus, FIG. 15 does not disclose a substantially planar distal end wall or the pocket having an annular wall as required by the present claims.

Therefore, Appellant respectfully submits that Yoon fails to anticipate each and every element of claim 1 as Yoon fails to disclose, *inter alia*, a pocket having an annular wall configured and adapted to contact an outer surface of the surgical instrument or the pocket including a substantially planar distal end wall. Accordingly, since Yoon does not disclose or suggest each and every element of claim 1, Appellant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Yoon should be reversed. Since claims 2-9, 11, and 12 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Appellant respectfully submits that claims 2-9, 11, and 12 are also not anticipated under 35 U.S.C. §102(b) over Yoon and the rejection of claims 2-9, 11, and 12 should also be reversed.

2) Independent claim 15

As stated above, independent claim 15 recites the cap of the instrument introducer assembly defining a pocket including a substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge thereof, the distal end wall including an aperture formed in the pocket configured and adapted to stretch and

conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument.

Yoon discloses a valve including four valve members of flaps, each having a generally curved triangular shape to sealingly mate with one another when closed and "to form a hemispherical or rounded wall closing the distal end of the tubular body" and thus fails to disclose a substantially planar distal end wall. Moreover, Yoon also fails to disclose or illustrate a pocket with an annular wall being in contact with an outer surface of the surgical instrument along substantially the length of the pocket.

Thus, Yoon clearly fails to disclose or suggest an elastomeric cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge thereof as required by claim 15.

Therefore, Appellant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Yoon should be reversed. Since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 1, Appellant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Yoon and the rejection of claims 16-19 should also be reversed.

3) **Independent claim 21**

Independent claim 21 recites, in pertinent part, a method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising, *inter alia*, the step of providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein.

Yoon discloses a valve including four valve members of flaps, each having a generally curved triangular shape to sealingly mate with one another when closed and "to form a hemispherical or rounded wall closing the distal end of the tubular body" and thus fails to disclose a substantially planar distal end wall. Moreover, Yoon also fails to disclose or illustrate a pocket with an annular wall being in contact with an outer surface of the surgical instrument along substantially the length of the pocket.

Thus, Yoon clearly fails to disclose or suggest providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of

the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein as required by claim 21.

Therefore, Appellant respectfully submits that the rejection of claim 21 under 35 U.S.C. §102(b) in view of Yoon should be reversed.

4) Independent claim 22

Independent claim 22 recites, in pertinent part, a method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising, *inter alia*, the step of providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein.

Yoon discloses a valve including four valve members of flaps, each having a generally curved triangular shape to sealingly mate with one another when closed and "to form a hemispherical or rounded wall closing the distal end of the tubular body" and thus fails to disclose a substantially planar distal end wall. Moreover, Yoon also fails to disclose or illustrate a pocket with an annular wall being in contact with an outer surface of the surgical instrument along substantially the length of the pocket.

Thus, Yoon clearly fails to disclose or suggest providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein as required by claim 22.

Therefore, Appellant respectfully submits that the rejection of claim 22 under 35 U.S.C. §102(b) in view of Yoon should be reversed.

5) Independent claim 23

As stated above, independent claim 23 recites the distal end portion of the instrument introducer defining a pocket including a substantially circular distal end wall and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the distal end wall of the distal end portion includes an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough, and further wherein the aperture has a smaller diameter than a diameter of the circular distal end wall, and wherein the aperture is provided with a region of weakened strength.

Yoon fails to disclose or illustrate a pocket with an annular wall being in contact with an outer surface of the surgical instrument along substantially the length of the pocket.

Thus, Yoon clearly fails to disclose or suggest an instrument introducer assembly including a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of the surgical instrument and facilitate passage of the surgical instrument therethrough as required by claim 23.

Therefore, Appellant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Yoon should be reversed.

C) Claim 10 is patentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,752,970 to Yoon et al. in view of U.S. Patent No. 5,634,937 to Mollenauer et al.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No. 5,634,937 to Mollenauer et al. (hereinafter, Mollenauer). Appellant respectfully submits that Yoon and Mollenauer, either alone or in combination, fail to teach or suggest the claimed apparatus.

As stated above, Yoon fails to disclose, among other things, a distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough, as called for in claim 1.

Mollenauer fails to cure the deficiencies of Yoon. Mollenauer is relied upon for the recitation of a polypropylene introducer body. Because Mollenauer fails to disclose or suggest a surgical instrument and instrument introducer assembly as recited in independent claim 1, no proper combination of Yoon and Mollenauer can render claim 1 obvious.

As claim 10 depends from claim 1, and contains all the features of claim 1, Appellant respectfully submits that the subject matter of claim 10 as a whole is patentable over Yoon in view of Mollenauer for at least the reasons presented above regarding the patentability of claim 1. Accordingly, in view of the foregoing, since Mollenauer fails to cure the deficiencies of Yoon, Appellant submits that the subject matter of claim 10 as a whole is allowable under 35 U.S.C. §103(a) over Yoon and Mollenauer and the rejection of claim 10 should be reversed.

D) Claims 14 and 20 are patentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,752,970 to Yoon et al. in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al.

Claims 14 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al. (hereinafter, Staskin). Appellant respectfully submits that Yoon and Staskin, either alone or in combination, fail to teach or suggest the claimed apparatus.

As stated above, Yoon fails to disclose, among other things, a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical

instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough, as called for in claims 1 and 15.

Appellant submits that Staskin fails to cure the deficiencies of Yoon. Staskin is relied upon by the Examiner for the recitation of a distal end portion having a frustoconical profile including a concave annular side wall. Appellant submits that since Staskin fails to disclose or suggest a surgical instrument and introducer assembly as recited in independent claims 1 and 15, no proper combination of Yoon and Staskin can render claims 1 and 15 obvious.

Furthermore, Staskin discloses a sling delivery system with a dilator. The dilator is attached to a needle through a shoulder on the dilator and corresponding recess in the needle. The dilator and needle are attached and not separated thereafter. (See Para. [0158] of Staskin).

As claim 14 depends from claim 1, and contains all the features of claim 1, Appellant respectfully submits that the subject matter of claim 14 as a whole is patentable over Yoon in view of Staskin for at least the reasons presented above regarding the patentability of claim 1. Furthermore, claim 20 depends from claim 15, and contains all the features of claim 15. Appellant submits that the subject matter of claim 20 as a whole is patentable over Yoon in view of Staskin for the reasons presented above regarding the patentability of claim 15. Accordingly, since Staskin fails to cure the deficiencies of Yoon, Appellant submits that the subject matter of claims 14 and 20 as a whole is allowable under 35 U.S.C. §103(a) over Yoon and Staskin and the rejection of claims 14 and 20 should be reversed.

VIII. CONCLUSION

In view of the foregoing remarks, Appellant respectfully submits that all of the claims now pending in this application, namely, claims 1-23 are in condition for allowance. Early and favorable reconsideration of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefore.

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,

Francesco Sardone
Reg. No.: 47,918
Attorney for Appellant

Carter, DeLuca, Farrell & Schmidt LLP
445 Broad Hollow Road – Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

IX. CLAIMS APPENDIX

1. (Rejected) A surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body opening of a patient, comprising:

a surgical instrument for performing a surgical procedure; and

an instrument introducer assembly including:

a tubular body portion defining a lumen therethrough, the tubular body portion having a proximal end and a distal end; and

a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation to the surgical instrument;

wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough.

2. (Rejected) The instrument introducer according to claim 1, wherein the distal end portion includes an annular side wall depending from an outer terminal edge thereof.

3. (Rejected) The instrument introducer according to claim 2, wherein the distal end portion is made from an elastomeric material.

4. (Rejected) The instrument introducer according to claim 2, wherein the distal end wall of the distal end portion includes an aperture formed therein.

5. (Rejected) The instrument introducer according claim 4, wherein the aperture is coaxially aligned with a central longitudinal axis of the tubular body portion.

6. (Rejected) The instrument introducer according to claim 4, wherein the distal end portion is secured to the distal end of the tubular body portion such that the annular side wall at least partially overlaps the distal end of the tubular body portion.

7. (Rejected) The instrument introducer according to claim 6, wherein the distal end portion is secured to the distal end of the tubular body portion such that the annular side wall completely overlaps the distal end of the tubular body portion.

8. (Rejected) The instrument introducer according to claim 4, wherein a proximal terminal edge of the annular side wall of the distal end portion is secured to a distal terminal edge of the distal end of the tubular body.

9. (Rejected) The instrument introducer according to claim 7, wherein the distal end portion is secured to the distal end of the tubular body by at least one of fusing, overmolding, gluing and bonding.

10. (Rejected) The instrument introducer according to claim 4, wherein the tubular body portion is fabricated from polypropylene.

11. (Rejected) The instrument introducer according to claim 4, further including a flange extending radially outward from the proximal end of the tubular body portion.

12. (Rejected) The instrument introducer according to claim 3, wherein the distal end wall of the distal end portion is provided with a region of weakened strength.

13. (Rejected) The instrument introducer according to claim 12, wherein the region of weakened strength includes at least one of score lines, perforations, webbing and reduced thickness.

14. (Rejected) The instrument introducer according to claim 4, wherein the distal end portion has a frustoconical profile including a concave annular side wall.

15. (Rejected) A surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body of a patient, comprising:

a surgical instrument for performing a surgical procedure; and

an instrument introducer assembly including:

a hollow elongate cylindrical body including a distal end portion terminating in a distal edge and a proximal end portion, the cylindrical body defining a central longitudinal axis; and

an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge thereof, the distal end wall including an aperture formed in the pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein a center of the aperture is coaxially aligned with the central longitudinal axis;

wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

16. (Rejected) The instrument introducer according to claim 15, wherein the cylindrical body is configured and adapted to receive a surgical instrument therethrough.

17. (Rejected) The instrument introducer according to claim 15, further including a flange extending radially outward from a proximal terminal edge of the proximal end portion of the cylindrical body.

18. (Rejected) The instrument introducer according to claim 15, wherein the cap is secured to the distal end of the cylindrical body such that the distal end wall of the cap is spaced a distance from the distal terminal edge of the cylindrical body.

19. (Rejected) The instrument introducer according to claim 15, wherein the cap is secured to the distal end of the cylindrical body such that a proximal terminal edge of the annular side wall is secured to the distal terminal edge of the cylindrical body.

20. (Rejected) The instrument introducer according to claim 15, wherein the distal end portion has a frustoconical profile including a concave annular side wall.

21. (Rejected) A method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising the steps of:

providing a surgical instrument for performing a surgical procedure;

providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein;

inserting the distal end of the instrument introducer into the cavity or body opening of the patient;

inserting the surgical instrument into the lumen of the tubular body of the instrument introducer through a proximal end of the tubular body; and

advancing the surgical instrument through the lumen of the tubular body of the instrument introducer thereby stretching the instrument introducer such that the aperture of the distal end wall stretches and conforms to a shape of the outer surface of the surgical instrument until a distal end of the surgical instrument projects out through the aperture of the cap, wherein the cap creates a seal around the perimeter of the surgical instrument extending therefrom.

22. (Rejected) A method of introducing a surgical instrument into a cavity or a body opening of a patient, comprising the steps of:

providing a surgical instrument for performing a surgical procedure;

providing an instrument introducer assembly, wherein the instrument introducer includes a hollow tubular body having a distal end portion and a proximal end portion defining a lumen therebetween, and a resilient cap secured to the distal end of the tubular body, the cap defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall having an aperture formed therein;

inserting a distal end of the surgical instrument into a proximal end of the tubular body of the instrument introducer;

inserting the distal end of the surgical instrument, having the instrument introducer placed thereon, into the cavity or body opening of the patient; and

advancing the surgical instrument through the instrument introducer thereby stretching the instrument introducer such that the aperture of the distal end wall stretches and conforms to a shape of the outer surface of the surgical instrument until the distal end of the surgical instrument projects out through the aperture of the cap, wherein the cap creates a seal around the perimeter of the surgical instrument extending therefrom.

23. (Rejected) A surgical instrument and instrument introducer assembly for facilitating the insertion of the surgical instrument into a cavity or a body opening of a patient, comprising:

a surgical instrument for performing a surgical procedure; and

an instrument introducer assembly including:

a tubular body portion defining a lumen therethrough, the tubular body portion having a proximal end and a distal end; and

a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including:

a substantially circular distal end wall having a diameter smaller than a diameter of the tubular body portion; and

an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of the surgical instrument and facilitate passage of the surgical instrument therethrough;

wherein the distal end wall of the distal end portion includes an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument

stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough, and further wherein the aperture has a smaller diameter than a diameter of the circular distal end wall, and wherein the aperture is provided with a region of weakened strength.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None